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EXAMINER	
BAGGOT, BRENDAN O	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,665	KUTCHAN ET AL.	
	Examiner	Art Unit	
	Brendan O. Baggot	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 43-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/26/01; 12/23/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction / Election

1. The Office acknowledges the receipt of Applicant's election restriction filed 7 December 2005. Applicant elects Group I and polynucleotides encoding SEQ ID NO:26 with traverse. Applicant's traversals have been carefully considered but are deemed not persuasive for the following reasons. Applicant traverses primarily that the groups can be used together, each of the sequences encodes a codeinone reductase-like molecule, up to 10 independent and distinct nucleotide sequences should be examined in a single application, and all inventions and all sequences should be considered a single invention united by a single technical feature. Regarding the special technical feature, Applicant has admitted that four different amino acid sequences and the corresponding coding sequences are being claimed (see page 12 of Response of 7 December 2005). It is not understood how four distinct sequences constitute a single technical feature. Furthermore, Applicant is actually claiming a multitude of sequence variants, fragments, alleles, and analogs (see Claim 1), rather than four particular sequences. The prior art cited by the Examiner does indeed teach the technical features broadly recited in the claims. Thus, the technical features are not "special" and unity of invention does not exist.

With regard to the sequences, Office resources can no longer support searching multiple sequences in the same application. Moreover, the cited portion of the M.P.E.P. is directed to EST oligonucleotide fragments, rather than to full-length protein-encoding

sequences. Also, "one" is encompassed by the "up to ten" as recited in the M.P.E.P. M.P.E.P.§ 803.04. Furthermore, while these sequences may encode codeinone reductase-like proteins, they have different K_ms, pIs, and nucleotide sequences and thus are not unique to the instant application. That is, other codeinone reductase-like sequences are known in the art (Lenz, et al, p. 132). Accordingly, this restriction is made FINAL.

Furthermore, it is noted that claims 59-62 are drawn to polynucleotides described by the Applicant to be four different alleles each represented by a different microorganism transformed with each of apparently 4 different sequences. It appears that each claim may be directed to a particular cDNA clone namely cor1.1-1.4 as recited on page 14 of the specification, line 10 and as depicted in Figures 10-13. However, it is unclear which of these claims encodes SEQ ID No:26, if any. Accordingly, claims 59-62 are withdrawn from examination as being drawn to non-elected sequences. Applicant is invited to provide the required information regarding the correspondence of the claims 59-62 to SEQ ID NOs: 20-23 – recited in claim 3 – to SEQ ID NOs: 26-29. Such information should be provided in the form of declaration under 37 C.F.R. §1.132.

Claims 1-62 are pending. Claims 1-19 and 43-46 and polynucleotides encoding SEQ ID NO: 26 are examined in the instant action.

2. Applicant's paper sequence listing has been entered.

Information Disclosure Statement

3. An initialed and dated copy of Applicant's IDSs filed 12/18/02 and 9/26/01 are attached.

Specification

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. See M.P.E.P. § 608.01(b); MPEP § 1893.03(e).

5. Tables 1 and 2 on pages 16 and 16a of the specification are objected to for their inclusion of drawings that should be presented in the form of Figures. The diagrams of plant parts in these tables will not be reproduced faithfully. If these drawings are not essential to the Tables, Applicant may provide an amendment to the specification under 37 C.F.R. 1.121(b) which replaces these Tables with drawings – free ones. If the drawings are essential, the Tables should be deleted from the specification and resubmitted as separate figures.

6. Applicant's recital of nucleotide sequences longer than 10 base pairs, e.g., page 12 of the specification, requires a SEQ ID NO for each sequence. 37 C.F.R. 1.821 - 1.825.

Drawings

7. See the objections listed above.

Claim Objections

8. Claim 3 is objected to because of the following informalities: Claim 3 lacks an "; and" subsequent to Claim part 3(a) and prior to part (b). All other claims similarly informal in their format are subject to this same requirement Appropriate correction is required.

Claim Rejections - 35 USC §112, first paragraph, enablement

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 46-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 10 is broadly drawn to any polynucleotide of any length and sequence derived from any source, which is complementary to any part of a codeinone reductase-encoding nucleic acid of any length or sequence. Claim 10 is also broadly drawn to any polynucleotide which is characterized only by the presence of a single nucleotide which is complementary to any part of a codeinone reductase-encoding nucleic acid of any length or sequence, and which polynucleotide further comprises a multitude of nucleotides of unspecified length or sequence.

With regard to sequences having less than 100% sequence identity and sequences that hybridize under "stringent" conditions, the breadth of these claims

encompasses unspecified base substitutions, deletions, additions, insertions, and combinations thereof without retaining function or with an inadequate function.

In contrast, the specification only provides guidance for the isolation of a polynucleotide encoding SEQ ID NO:26 from poppy, and tobacco transformation therewith. No guidance is provided regarding sequence domains which would be conserved throughout the broadly claimed genus of sequences, wherein said sequences domains are associated with codeinone reductase function. Furthermore, no guidance is provided regarding any alteration of alkaloid content, type or blend in tobacco, poppy, or any other plant transformed with the exemplified or non-exemplified sequences.

Hybridization to a given sequence, e.g., the codeinone reductase sequence, does not necessarily allow the making and using of the hybridizing sequence because sequences with very different function but only slightly different sequence will hybridize under even "high" stringency conditions. Van de Loo et al (1995 Proc. Natl. Acad. Sci. 92:6743) teach that sequences encoding fatty acid hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Broun et al, (1988, Science 282:1315-1317) teach that a change in only four amino acids will convert a 15 desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, if sequences are identified only by hybridization to known sequences that encode codeinone reductase activity, one cannot conclude on this basis alone that these sequences also will encode a protein having said activity without additional evidence of the functionality

or more knowledge of the particular structural features that are required for conferring this function.

Claims 43-46 are drawn to plant transformation with a polynucleotide which hybridizes to a codeinone reductase-encoding nucleic acid under conditions of unspecified stringency, including low and moderately stringent conditions; wherein said plant may be any species including oak, canola, corn, rice, tobacco, orchid, grapefruit, chrysanthemum, eggplant, carrot, gingko, palm, cactus, etc.; wherein said transformation results in the modification of alkaloid content, type, or blend. Thus claims 43-46 are broadly drawn to transformation of a multitude of unrelated plant species with a multitude of unrelated sequences of undefined lengths encoding a multitude of proteins of unspecified length and sequence, with unspecified function; for the alteration of type, content or blend of a multitude of unspecified alkaloids.

In contrast, the specification only provides guidance for the isolation of a polynucleotide encoding SEQ ID NO:26 from poppy, and tobacco transformation therewith. No guidance is provided regarding sequence domains which would be conserved throughout the broadly claimed genus of sequences, wherein said sequences domains are associated with codeinone reductase function. Furthermore, no guidance is provided regarding any alteration of alkaloid content, type or blend in tobacco, poppy, or any other plant transformed with the exemplified or non-exemplified sequences.

The retention of codeinone reductase activity following mutation or truncation of SEQ ID NO:26; or via the use of a multitude of non-exemplified sequences which

hybridize to a codeinone reductase-encoding sequence under conditions of unspecified stringency, or via the use of a multitude of non-exemplified sequences which comprise as little as a single nucleotide complementary to a single nucleotide present in a codeinone reductase-encoding sequence, is unpredictable.

Lazar et al (1988, Mol. Cell Biol. 8:1247-1252) teach that a replacement of aspartic acid at position 47 with an alanine or asparagines in transforming growth factor alpha had no effect, but that a replacement with serine or glutamic acid sharply reduced biological activity (see the abstract). Small changes in amino acid sequence can even completely modify enzymatic function; Broun et al (1988, Science 282:1315-1317) teach that a change of four amino acids converts an oleate 12-desaturase to a hydroxylase. Thus Lazaar et al and Broun et al demonstrated that one or a few amino acid substitutions could dramatically affect the biological activity and the structure-function characteristics of a protein.

Furthermore, the alteration of alkaloid type, content or blend following the transformation of any plant species – even those lacking (S) norcoclaurine synthase activity ((S) norcoclaurine synthase is the enzyme at the fork in the road leading to codeinone reductase) – with any exemplified or non-exemplified sequence is unpredictable, given the lack of particular metabolic pathways found in a multitude of unrelated plant species. Alkaloid metabolic pathways and the particular enzymes in the pathways in poppy or other plants) were previously unknown.

Liscombe et al (2005 Phytochemistry 66:2500-2520) found that benzylisoquinoline alkaloids (BIAs), the upstream precursors for codeinone reductase

reactants, were not present in large numbers of plant species, e.g., they were present only sporadically in plants of the order Piperales and were not found in taxa that diverged before the eudicots (i.e., basal angiosperms, monocots, and commelinids)(abstract and p. 2513 first full paragraph on right hand side). Therefore, because the chemical substrates for codeinone reductase would not be present in any plant, plant transformation with codeinone reductase would have no effect and would produce no codeinone reductase product: namely codeine. (S)norcoclaurine synthase containing plants, according to Liscombe, would have the benzylisoquinoline alkaloids needed to make Applicant's invention enabled and operative subsequent to genetic recombination with an operable codeinone reductase expression cassette.

Additionally, five years after the filing of the instant application, instantly named inventors Kutchan and Zenk, in *Millgate et al*, (Nature (2004) 431:413-414), taught that knowledge about the genes involved in the morphinan branch of the pathway is sparse (p. 413, 1st column, 2nd paragraph). In fact, the gene for norcoclaurine synthase, the first committed step of the benzylisoquinoline alkaloid pathway, was unknown prior to 2002 much less enabled by Applicant (Samanani and Facchini, J, (2002). Biol. Chem., Vol. 277, Issue 37, 33878-883).

Moreover, even if a plant inherently containing the particular alkaloid metabolic pathway were transformed with a gene encoding the exemplified enzyme in that pathway, it is unclear that any change in the accumulation of any alkaloid product would be observed, given the existence of feedback inhibition, cellular compartmentation of pathways, the interconnectedness of the alkaloid pathway, substrate degradation and

turnover, and other forms of compensation/homeostasis at various stages in the pathway. Applicant is directed to Sweetlove et al, which teaches the transformation of whole plants for the accumulation of desired products via transformation with genes encoding enzymes involved in the synthesis of that product is unpredictable. Sweetlove et al found no difference in starch content, tuber number, tuber weight, or metabolite content between potatoes transformed with a gene encoding AGP and control plants, despite AGP enzyme activity four fold higher in transformed plants versus controls. (1996, Biochem. J. 320: 493-498, p. 495, entire page, and page 497, right column, paragraph 3).

Given the claim breadth, lack of guidance, and unpredictability as stated above, undue experimentation would have been required by one skilled in the art to identify and isolate a multitude of non-exemplified sequence variants which encode proteins which retain codeinone reductase activity. Undue experimentation would have also been required to obtain a multitude of transformed plants of a multitude of unrelated species, transformed with a multitude of exemplified or non-exemplified sequences, and to evaluate said sequences and transformants for their ability to alter alkaloid content, blend or type in a multitude of exemplified or non-exemplified plant species.

Claim Rejections - 35 USC §112, first paragraph, enablement/deposit

Claims 17-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 17-19 are drawn to particular plasmids. The specification does not provide any guidance regarding the composition of said plasmids, regarding any particular promoters, coding sequences, or other sequences. The specification does not even recite the claimed plasmids. Accordingly, one skilled in the art would not know how to make and/or use said plasmids.

The invention appears to employ novel plasmids contained in microorganisms. Since the plasmid contained in the microorganism is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism containing the plasmid, and it is not apparent if the microorganism is readily available to the public. Thus, a deposit is required for enablement purpose. Applicant has deposited a microorganism containing the plasmid, but the availability of the deposit is unclear. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
(e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC §112, first paragraph, written description

Claims 10 and 46-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 10 is broadly drawn to any polynucleotide of any length and sequence derived from any source, which is complementary to any part of a codeinone reductase-encoding nucleic acid of any length or sequence. Claim 10 is also broadly drawn to any polynucleotide which is characterized only by the presence of a single nucleotide which is complementary to any part of a codeinone reductase-encoding nucleic acid of any

length or sequence, and which polynucleotide further comprises a multitude of nucleotides of unspecified length or sequence.

Claims 43-46 are drawn to plant transformation with a polynucleotide which hybridizes to a codeinone reductase-encoding nucleic acid under conditions of unspecified stringency, including low and moderately stringent conditions. Thus claims 43-46 are broadly drawn to plant transformation with a multitude of unrelated sequences of undefined lengths encoding a multitude of proteins of unspecified length and sequence, with unspecified function.

In contrast, the specification only provides guidance for the isolation of a polynucleotide encoding SEQ ID NO:26 from poppy, and to tobacco transformation therewith. No guidance is provided regarding sequence domains which would be conserved throughout the broadly claimed genus of sequences, wherein said sequences domains are associated with codeinone reductase function.

It is well established that sequence similarity is not sufficient to determine functionality of a coding sequence. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and "overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar function's" (the last sentence of the first paragraph of page 2484). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph).

In addition, Smith et al (Nature Biotechnology 15: 1222-1223, November 1997) teach that "there are numerous cases in which proteins of very different functions are homologous" (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133, April 1999) discusses the problem of inferring function from homology, stating that "most homologs must have different molecular and cellular functions" (see the second full paragraph of the second column of page 132, for example).

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. Id.

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

> [T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. *See* The Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 U.S.C. §112, second paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-19, 46-48 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. *See* MPEP 2171.

Claims 3, and 46-48 are rejected under 35 U.S.C. §35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Applicant recites "stringent" conditions without defining such conditions. The ordinarily skilled artisan would be unclear as to the precise meaning of the term; even "high stringency" is capable of separate and distinct meanings.

Claims 1, 3, 8 and 46-48 and dependents are indefinite in their recitation "is as set forth in" or "as set forth in", as it is unclear whether the subsequently recited SEQ ID NOs are required claim elements, or whether they are merely exemplary. Replacement of "is as set forth in" with "is" or "comprises" in claims 1, 8, and 46-48; and replacement of "as set forth in" with "of" in Claim 3, would overcome this rejection.

Claims 17-19 are indefinite in their recitation of various plasmid names, as it is unclear to what these names correspond. The specification does not recite these plasmid names or provide any information regarding their components.

Clarification and/or correction are required.

Claim Rejections - 35 U.S.C. §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Hiatt, et al (US 4,801,540, 1989). As written, claim 10 is drawn to an isolated polynucleotide encoding SEQ ID NO: 26. "Part of" is interpreted to include a single nucleotide base pair.

Hiatt, et al teaches an isolated and purified polynucleotide sequence (see Figure 1, e.g.) that shares at least one nucleotide base pair with SEQ ID NO: 26, which would be complementary to one base of a polynucleotide encoding SEQ ID NO:26 and as such, Hiatt, et al anticipates the claimed invention (see Claim 10), and therefore claim 10 stands rejected.

12. Claims 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Hiatt et al, Welle et al , van der Krol, et al., and Tsukaya, et al. Claims 46-48 are drawn to methods of transforming a plant cell or plant with a polynucleotide which

hybridizes under conditions of unspecified stringency, including low stringency, to a polynucleotide which encodes SEQ ID NO:26. Hiatt et al (US 4,801,540, 1989), in 1989, taught a transformed tomato plant, with an antisense oriented isolated and purified polynucleotide sequence of at least one nucleotide base and capable of hybridizing to Applicant's codeinone reductase polynucleotide sequence under low stringency conditions (see, e.g., Figure 1). Moreover, both van der Krol, et al and Tsukaya, et al teach plant transformation – Petunia and Arabidopsis respectively – with chalcone synthase similar to Applicant's sequence. *See* both abstracts at least. Chalcone synthase encoding sequences would inherently hybridize with Applicant's sequence under low or moderate stringency conditions. Welle et al, ((1991) Eur. J. Biochem. 196:423-430), cited in Applicant's specification, teach heterologous expression of a soybean NAD(P)H dependent 6'-deoxychalcone synthase, 53% identical to Applicant's sequence and which would inherently hybridize under conditions of unspecified stringency, including low stringency, to a polynucleotide which encodes SEQ ID NO:26. (*See* specification, page 14: line 17). Therefore, Claims 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Hiatt et al., Welle et al, van der Krol et al and Tsukaya et al.

13. Claims 1-9, 11-19, and 43-45 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated nucleic acid molecule encoding SEQ ID NO: 26.

Remarks

Claims 1-19 and 43-46 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brendan O. Baggot whose telephone number is 571/272-5265. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571/272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

2/16/06

Brendan O. Baggot
Patent Examiner
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bob

DAVID T. FOX
PRIMARY EXAMINER
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